

EU Declaration of Conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany		
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701		
Product Name	gigazyme[®] X-tra		
Basic UDI-DI Code acc. to Art. 26 2017/745	4032651BSC00000039AM Z12011385		
Intended Purpose	cleaning and disinfection agent for manual reprocessing of medical devices		
Risk Class according to Regulation 2017/745	II a	Annex	VIII
		rule	16
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH		
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297		
Conformity Assessment Procedure according to Regulation 2017/745	Annex	IX	Chapter I, II section 4 and III
Certificates	Annex	IX	004567 MDR2017Q 004567 MDR2017B EN ISO 13485 004567 MP2016
Version	1-0		

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this declaration

Norderstedt 15.06.2023
ppa.


Dr. Sven Pflöging
Schülke & Mayr GmbH
Chief Commercial Officer

15.06.2023
ppa.


Lars Lemke
Schülke & Mayr GmbH
Chief Operating Officer